

GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

A registered entity is required by law (42 CFR 73.17, 9 CFR 121 and 7 CFR 331) to contact CDC or APHIS immediately upon discovery of a theft or a release of a select agent and toxin not authorized under a federal act. The agency that the Responsible Official (RO) should contact is determined by the type of select agent or toxin involved in the incident. For HHS agents, the Responsible Official (RO) must contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For HHS/USDA overlap agents, the RO must contact both APHIS and CDC at the numbers listed (for USDA after hours call 1-866-994-5678). For USDA agents, the RO must contact APHIS (telephone: 301-734-5960, or facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppg/permits.

The RO should contact the appropriate agency immediately upon discovery of loss, theft, or occurrence of release of the select agents and toxins to explain the circumstances. Notification of the proper agencies is important to assure that emergency response efforts, including medical intervention and follow-up surveillance of human or other animals potentially exposed by release of the select agents and toxins(s), are accomplished in a timely matter, if appropriate. For release of HHS select agents or toxins, the RO should also notify the local and State Health Department. For USDA agents, the State Veterinarian should be contacted; for restricted plant pathogens, the State Plant Regulatory Official should be notified. For HHS/USDA overlap agents both the State Veterinarian and State Health Departments should be notified. In the case of theft or loss, the local police and Department of Justice should be notified, as appropriate.

The theft, loss, or release of an HHS select agent or toxin must be reported immediately upon discovery to CDC by telephone (404-498-2255), facsimile (404-498-2265), or e-mail (lrsat@cdc.gov). The theft, loss, or release of a USDA select agent or toxin must be reported immediately upon discovery by calling APHIS at 1-866-994-5678 and following the instruction prompt. The theft, loss, or release of an HHS/USDA select agent or toxin must be reported immediately upon discovery to both CDC and APHIS. After the initial reporting by telephone, this form should be sent directly to CDC or APHIS, as appropriate, within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. This requirement is not satisfied by reporting the theft or significant loss in any other manner. The entity is required to keep a copy of the notification form.

INSTRUCTIONS

RO must complete Sections 1 and 4. Section 2 should be completed for those entities for which a loss or theft has occurred. Section 3 should be completed for those entities that have a release of select agents or toxins. The RO must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-5960. This guidance document and form are also available at http://www.aphis.usda.gov/vs/ncie and http://www.aphis.usda.gov/ppq/permits.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA agents, return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

For HHS/USDA overlap select agents and toxins, return forms to: both CDC and APHIS at the addresses provided.

This form shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.



Entity name

Entity address (NOT a post office address)

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS



Zip Code

CDC#

State

Read all instructions carefully before completing the report. This report must be submitted by the Responsible Official. Answer all items completely and type or print in ink. The report must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For HHS/USDA overlap agents submit the form to both CDC and APHIS. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

SECTION 1 - TO BE COMPLETED BY RESPONSIBLE OFFICIAL

City

Entity registration number

APHIS#

| Responsible Official (RO) | Telephone | FAX | | E-mail | | | | |
|---|-------------------------------|------------------------|--|-------------------------|----------|----|--|--|
| Address (NOT a post office | - | City | | State | Zip Code | | | |
| An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: Yes No | | | | | | | | |
| SECTION 2 – TO BE COMPLETED ONLY FOR REPORTING LOSS OR THEFT OF SELECT AGENTS AND TOXINS | | | | | | | | |
| IF LOS | T ON SITE OR THEFT H | IAS OCCURRED P | ROVIDE THE | FOLLOWING INFO | RMATIC | ON | | |
| Provide a list of all missing | select agents and toxins (Com | plete Section 4) | | | | | | |
| Date loss or theft noted | | Name of principal inve | of principal investigator for laboratory with select agents and toxins | | | | | |
| Laboratory building and room Name and | | | d telephone number of local police department notified | | | | | |
| Type of theft (Night break in, armed robbery, etc.) Symbols or markings on containers (if any) | | | | | | | | |
| Provide a detailed summary of events (attach additional sheets if necessary): | | | | | | | | |
| | | | | | | | | |
| IF LOST OR STOLEN IN TRANSIT PROVIDE THE FOLLOWING INFORMATION | | | | | | | | |
| Provide a complete list of missing select agents and toxins (Complete Section 4) | | | | | | | | |
| Attach a copy of the Form EA-101 that was associated with this shipment | | | | | | | | |
| Name of carrier | | | Airway | bill number/tracking nu | mber | | | |
| Provide a detailed summary of events (attach additional sheets if necessary): | | | | | | | | |
| | | | | | | | | |
| Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary): | | | | | | | | |
| | | | | | | | | |

| | SE | SENDER INFORMATION | | RECIPIENT INFORMATION | | | |
|--|------------------------|---------------------|--|---|----------|--|--|
| Name of person | | | | | | | |
| Name of entity | | | | | | | |
| CDC/APHIS registration number | CDC | APHIS | | CDC | APHIS | | |
| PHS/USDA import permit number | PHS | USD |)A | PHS | USDA | | |
| Date shipped | | | | | - ' | | |
| Telephone | | | | | | | |
| FAX | | | | | | | |
| CDC confirmation number from transfer form: | | | APHIS confirmat | APHIS confirmation number from transfer form: | | | |
| Package with select agents and toxins received by requestor Yes No | | | Package with select agents and toxins was tampered with Yes No | | | | |
| Other contents of package (e.g., coo | plant type): | | , | | | | |
| | | | | | | | |
| | | | | | | | |
| SEC | CTION 3 – TO BE | | ONLY FOR RAND TOXINS | ELEASE OF SE | LECT | | |
| Provide a list of all select agents and | I toxins released (Co | mplete Section 4) | | | | | |
| Date of release Time of release | ase Name of | principal investiga | ator for laboratory w | vith select agents and | d toxins | | |
| Location of exposure or release (give | e laboratory building, | room, area and su | urface or space inv | olved) | | | |
| Name and telephone number of loca | l and ar atata haalth | 1 1 1'6' 1 | I Niana and tal | ephone number of em | | | |

| | SECTION 3 | B – TO BE COMPLETE AGENTS | _ | | OF SELECT | | | |
|--|--|--|---|--------------------------|--|--|--|--|
| Provide a list of all se | lect agents and toxins re | eleased (Complete Section 4 |) | | | | | |
| Date of release | Time of release | Name of principal investig | Name of principal investigator for laboratory with select agents and toxins | | | | | |
| Location of exposure | or release (give laborato | ory building, room, area and | surface o | r space involved) | | | | |
| Name and telephone | Name and telephone number of local and or state health dept. notified Name and telephone number of emergency responders | | | | | | | |
| Biosafety level of laborate | oratory where exposure | occurred | | | | | | |
| Names of person(s) in | nvolved in exposure (atta | ach additional sheet if neces | ssary) I | Number of animals exp | posed | | | |
| Injuries No | Yes (If Yes, give n | ames and occupations of inc | lividuals i | njured) | | | | |
| | | | | | | | | |
| Exposures No | Yes (If Yes, giv | e names and occupations of | individua | ıls exposed) | | | | |
| | | | | | | | | |
| Medical treatment wa | s required No | Yes (If Yes, explain) | | | | | | |
| Provide a detailed su understood): | mmary of events (attach | additional sheets if necessa | ary; provid | de sufficient informatio | n so that the severity of the release can be | | | |
| | | | | | | | | |
| | | | | | | | | |
| Provide a summary o Called ambulance Called police dep | e Called fire depart | tment Closed laborator Other (explain | , | Closed building | Consulted MSDS or chemical database | | | |

| Pr | Provide a summary of clean up actions taken (attach additional sheets if necessary): | | | | | | |
|----|--|-------------------------------------|------------------------------|-----------------------------------|--|-------------------|--|
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| | | SECTION 4 – TO BE COMPLETED BY AL | L APPLICAN | TS | | | |
| | LIST | OF SELECT AGENTS AND TOXINS LOST, S | STOLEN OR F | RELEASED | | | |
| | Select Agents and Toxins | Characterization of Agent | Number of Vials | Form (powder/liquid/ slant) | Vol or Wt per Vial (e.g., ml, mg, ng) | Total Quantity | Concentration/Vial (e.g., 10 ⁸ pfu/ml) |
| | Botulinum toxin | Neurotoxin A | 50 | liquid | 5 ml | 250 ml | 1 mg/ml |
| | Bacillus anthracis | Ames strain | 25 | liquid | 1 ml | 25 ml | 10 ⁸ /ml |
| | Ebola virus | Zaire | 10 | liquid | 1 ml | 10 ml | 10 ⁷ pfu/ml |
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| Thereby Certify that the information contained on this i | ini is the and correct to the best of my knowledge. I understand that it i knowledge provide a laise statement on any part of this form, or its attachments |
|--|---|
| may be subject to criminal fines and/or imprisonment. | further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment. |
| Signature of Responsible Official (RO): | Typed or printed name of RO: |
| Date: | |

Public reporting burden: Public reporting burden of providing this information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).